DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

9 4025

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-03-31

May 16, 2003

Lucille Tournour, President
Bagel King Bakery, Incorporated
5021 Edgewater Drive
Orlando, Florida 32810

Dear Mrs. Tournour:

Inspection of your bakery operation located at the above address on February 13-21, 2003, by FDA Investigator Stephanie S. Milan, revealed serious violations of the Federal Food, Drug, and Cosmetic Act (the Act). The Investigator documented significant deviations from the Food Labeling Regulations in Title 21, Code of Federal Regulations, Part 101 (21 CFR 101), causing your packaged bagel products to be misbranded within the meaning of Section 403 of the Act (21 U.S.C. § 343).

Our review of your 6 count 23 ounce poly bag labels for at least 10 varieties of "Best Bagels U.S.A." reveals that the products are misbranded in that their labels fail to bear nutrition labeling as required by Section 403(q)(1) of the Act (21 U.S.C. § 343(q)(1)) and 21 CFR 101.9. These products are not exempt from this requirement under Section 403(q)(5)(21 U.S.C. § 343(q)(5)) of the Act because they were labeled on or after May 8, 1996, and they are being sold directly to consumers. The labels for these products also bear the nutrient content claims "no fat" and "no cholesterol" without the required nutrition labeling.

In addition, your bagel products are further misbranded within the meaning of Section 403(i)(2)(21 U.S.C.§ 343(i)(2))in that the correct common or usual name for each ingredient is not listed on the labels for any of the 10 varieties. The same generic list of ingredients is used on the poly bag label for all 10 varieties of the product.

During the inspection, the investigator also documented numerous deviations from the Good Manufacturing Practice (GMP) Regulations for Foods in 21 CFR Part 110. Objectionable conditions observed included poor employee practices, inadequate sanitizing procedures, direct food contact with wooden equipment that was pitted, cracked and splintered, reuse of single service aluminum pans without washing and sanitizing, structural defects, a faulty refrigeration unit, and inadequate monitoring of storage temperature.

The above violations are not meant to be an all-inclusive list of deficiencies regarding food products produced and labeled by your firm. Other GMP and label violations can also subject your food products to regulatory action. It is your responsibility to assure that all of your products are produced using good manufacturing practices and that they are labeled in compliance with the Act, and the requirements of the Food Labeling Regulations. You should take prompt action to correct these violations. Failure to correct these violations may result in regulatory action, including seizure and/or injunction, without further notice.

Please respond in writing within 15 working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these violations. Your response should include examples of your revised labels or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Your reply should be directed to Jimmy E. Walthall, Compliance Officer, U.S. Food and Drug Administration, 555 Winderly Place, Suite 200, Maitland, Florida, 32751, telephone (407) 475-4731.

Sincerely,

Emma R. Singleton
Director, Florida District